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(71) Applicant: **PRECISION VASCULAR SYSTEMS, INC.** [US/US]; 360 Wakara Way, Salt Lake City, UT 84108 (US).

(72) Inventors: **JACOBSEN, Stephen, C.**; 274 South 1200 East, Salt Lake City, UT 84108 (US). **LIPPERT, John**; 9006 North Jeremy Circle, Park City, UT 84098 (US). **DAVIS, Clark, C.**; 4564 Wallace Lane, Salt Lake City, UT 84117 (US). **BACKMAN, Kent**; 3299 Splendor Way, Salt Lake City, UT 84124 (US).

(74) Agents: NORTH, Vaughn, W. et al.; Thorpe, North & Western, LLP, P.O. Box 1219, Sandy, UT 84091-1219 (US).

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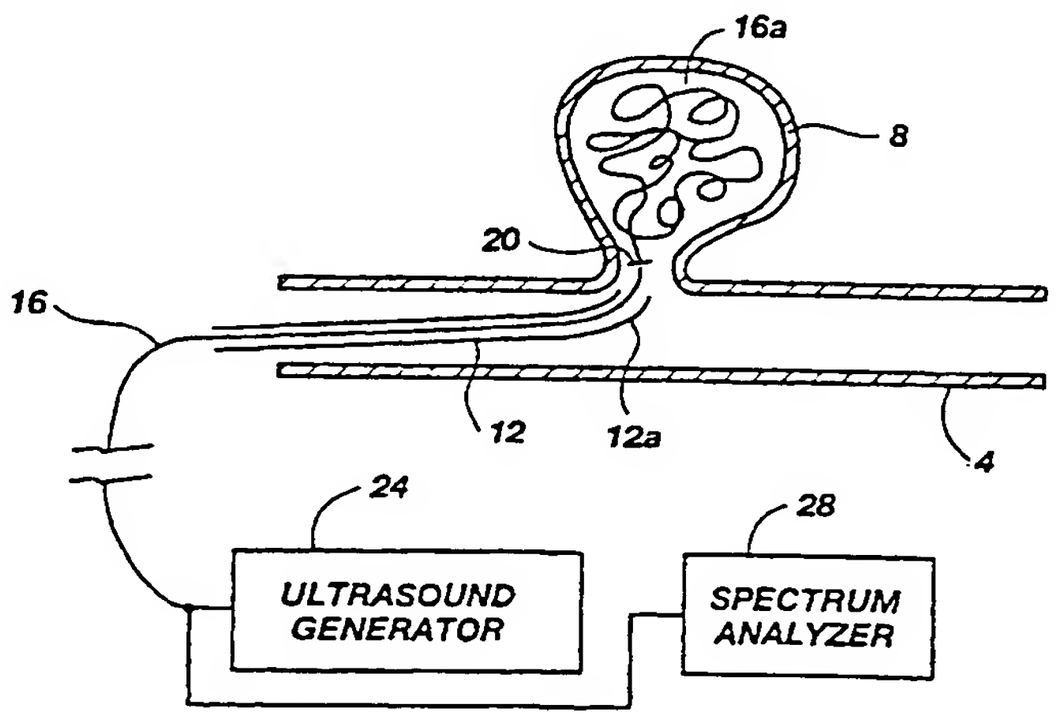
(54) Title: DETACHABLE COIL FOR ANEURYSM THERAPY



(57) Abstract: Apparatus and method are disclosed by which a hollow distal end portion of a wire may be deposited at selected sites in body passageways. The apparatus includes an elongate wire (16) (solid or hollow) having a distal end section for detachment and delivery to a target location, the wire (16) also having a discontinuity (20) located rearwardly of the distal end section for rupturing when vibrational energy is applied to the wire (16). The discontinuities may take the form of cuts (38) formed in the wire (30), reduced diameter sections (49) in the wire (40), adhesive, welded or soldered couplings between the wire (50, 55, 60) and the distal end section, or the wire (200) transitioning from the wire (200) to a large mass (204) disposed on the distal end section. A catheter (304) is coupled to or surrounds the elongate wire (302) to deliver therapeutic liquid to a target body location. The apparatus includes a vibrational energy source (400) couplable to the proximal end of the wire (16) for selectively applying vibrational energy to the wire (16) to travel to the discontinuity (20) and cause detachment of the end section.

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DETACHABLE COIL FOR ANEURYSM THERAPY

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to endovascular devices for occluding and/or stabilizing and sealing off vasculature or body passageways, tissue defects, and aneurysms. More specifically, the present invention relates to a method and apparatus for threading wires into body cavities and detaching end sections thereof using vibrational energy, for example, in the form of elastic waves.

2. State of the Art

A variety of methods have been developed for occluding and/or stabilizing and sealing off vasculature or body passageways, tissue defects and aneurysms with the use of endovascular catheters including injectable particles, injectable glue, and detachable coils and other devices. The use of detachable coils appears to be gaining widest acceptance for aneurysm therapy, perhaps because of the ease and precision of control of the delivery and disposition of the coil at the desired occlusion site.

One approach for delivering and detaching coils at an occlusion site involves forming or attaching the coil at the distal end of a wire, and then threading the coil and wire through a catheter until the coil is disposed at the occlusion site. An electric current is then applied to the proximal end of the wire and conducted through the wire to the point of origin or attachment of the coil where it causes the coil, for example, by electrolysis, to detach from the wire. See US Patent Nos. 5,569,245, 5,624,449, 5,122,136, 5,540,680, and 5,354,295.

Among the problems associated with the electrically detachable coil approach is the time necessary to effectuate detachment (which changes with increasing number of devices delivered), the lack of reliability that the coil will detach, discomfort with the use of a grounding needle (insertable in the flesh of the patient) required for the proper functioning of the device, generation of particulates from the detachment site (electrolysis), and inability to select the size of the coil in vivo.

In use, the wire is threaded through a vasculature or body passageway to a target location, and therapeutic fluid is injected through a catheter or hollow wire to the target location. Then vibrational energy is applied to the wire to cause the distal end section to detach and remain at the target location to occlude the passageway, and the remainder of the wire is withdrawn from the patient.

In accordance with one aspect of the invention, the discontinuity could include a cut in the wire, a hole, a reduced diameter section, an abrupt increase in mass, an adhesive, soldered or spot-welded joint which joins the distal end section to the wire, a coil soldered or adhesively attached to either the outer surface of a solid or hollow wire, or to the inner surface of a hollow wire, or a heat or chemically treated section. Alternatively, the distal end section could include a plurality of discontinuities, each adapted to rupture at a different vibrational levels or frequencies, to detach a selected portion of the distal end section which is distal to the discontinuity being ruptured.

Other objects, features and advantages of the invention will become apparent from a consideration of the following detailed description presented in connection with the accompanying drawings

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a side, fragmented, cross-sectional view of a wire made in accordance with the principles of the present invention, in which the proximal end of the wire is coupled to an ultrasound generator and the distal end of the wire is formed into a tangled mass disposed in an aneurysm;

FIGS. 2-3, 4A-4C, and 5-6 show side, fragmented views of different embodiments for providing discontinuities to allow detachment of end coil sections from delivery wires, all in accordance with the principles of the present invention;

FIG. 7 is a side, fragmented view of a hollow end coil section having a plurality of discontinuities for tuned resonator detachment, in accordance with the principles of the present invention;

with a coiled end section 16a. Wire 16 may be any long prismatic element, whether solid or hollow, and the end section 16a could be tangled, formed into specific shapes, etc. as well as being coiled.

A discontinuity 20 is formed between the end section 16a of the wire and the rest of the wire 16. The discontinuity 20 may take a variety of shapes and forms, so long as it is designed to rupture, break or separate when vibrational energy of a certain frequency and magnitude is applied to the wire 16. The vibrational energy source in the FIG. 1 embodiment is preferably an ultrasound generator 24, but could be something as simple as a striker, mallet, hammer, etc. for striking the wire 16 to cause mechanical vibrations to propagate to the discontinuity 20.

In use, the catheter 12 is threaded through a vasculature or body passageway to a site at which the end section 16a of the wire is to be disposed, such as the aneurysm 8 in FIG. 1. The purpose of such disposal, for example, is to provide an occlusion in the passageway to allow for coagulation of blood to prevent further flow, or, as in the FIG. 1 schematic, to cause scarring in the aneurysm 8 to thereby fill the aneurysm with scar tissue to prevent the bursting thereof, etc. The end section 16a is shown as being coiled or tangled but when threaded through the catheter 12 it would be straightened. Formation of a wire or coil with these properties is frequently accomplished by heat treating or other methods known in the art. Then when the end section 16a is pushed out the terminal end 12a of the catheter, the end section would resume the normally coiled or tangled condition as shown (enhanced also by body warmth).

After the end section 16a has been guided to the desired target site, the ultrasound generator 24 would be connected to the proximal end of the wire 16 and an ultrasound signal applied thereto. The frequency and amplitude of the signal (observed on a spectrum analyzer 28) would be selected to produce high stress in the discontinuity 20, fatiguing the wire so that it breaks, ruptures, or otherwise separates at the discontinuity, leaving the end section 16a in the aneurysm 8. Because the system uses vibrations in the ultrasonic range, the separation is accomplished rapidly, reliably and without pain to the subject. A

target site in a body passageway. A cut or diameter reduction 49 is also formed in the wire 40 to provide the desired discontinuity. A coil mass 47 might also be added about the wire 40 to further exaggerate the discontinuity. The cut 49 might advantageously be about ½ of the way through the wire 40 in the transverse direction to serve to rupture or separate when an ultrasound signal is applied to the wire.

FIG. 4A shows another embodiment of a discontinuity between a wire 50 and an end section 54, again including cuts 58. The terminal end of the wire 50 is attached by a section of adhesive 59 to the proximal end of the end section 54. The adhesive 59 is selected from materials that are somewhat brittle, such as sodium silicate, so that when an ultrasound signal is applied to the wire 50, the adhesive 59 will fracture to allow the end section 54 to separate from the wire 50. Alternatively, section 59 of wire 50 could be heat-treated or H+ embrittled to make the wire brittle at that location. As yet another alternative, section 59 could be chemically-treated, such as by etching, to make the wire weaker at that location.

FIG. 4B shows the discontinuity formed as a hole 51, whereas FIG. 4C shows the discontinuity as a spot weld 53 joining the wire 55 side-by-side to an end section 56. A coil mass 57 provides additional discontinuity. The process of spot welding heats the wire 55, making it more susceptible to fatigue and breaking. In fact, heating alone may be used to create a "discontinuity".

FIG. 5 shows an embodiment similar to that of FIG. 3 except that the discontinuity does not comprise a cut in either the wire 60 or end section 64. Rather, the discontinuity is formed at the joint or connection between the wire 60 and end section 64 wherein the wire is inserted in the hollow 64a of the end section and held in place by a blood soluble adhesive 68, such as sodium silicate. When the end section 64 is guided through a blood vessel by the wire 60 (i.e., through a catheter inserted in a blood vessel), blood enters the hollow 64a of the end section 64 which, along with blood contacting the adhesive 68 at the proximal end of the end section, operates to dissolve the adhesive and allow separation of the end section from the wire.

The detachment sites shown and described above are configured for detachment in the axial mode. However, torsional waves are advantageous when using a section of wire which has been provided with cuts to enhance its lateral flexibility. The cuts severely reduce the axial stiffness of the wire (particularly of hollow wire), but can be made in such a way as to not reduce the torsional stiffness of the wire as much. (See, e.g. U.S. Patent Application Ser. No. 08/568,493, filed Dec. 7, 1995). The cut wire therefore is more capable of transmission of torsional than of axial vibration. Where selective detachment is desired, the wave is required to travel through sections of cut wire to reach the various detachment sites. Consequently, the torsion mode is preferred for selective detachment of cut wire.

The cuts 84 create spring elements to isolate the intermediate uncut sections of the wire 80 which have a mass. When a vibrational energy wave at the resonant frequency of the spring/mass system is applied to the wire 80, the wire is excited longitudinally and the sections of mass between the cuts vibrate longitudinally at high amplitude which fatigues the spring elements (location of cuts) causing them to break. The wire 80 could advantageously be made of stainless steel or nickel titanium alloy.

FIGS. 8 and 9 show side, cross-sectional, fragmented views of a type of wave guide construction for transmitting vibrational energy along a wire surrounded by a catheter or sleeve. Referring to FIG. 8, there is shown a wire 90 disposed inside of a catheter or sleeve 94 but held out of touch from the sleeve by supports, for example, in the form of rings spaced apart longitudinally and uniformly along the length of the wire and sleeve. The supports 98 are positioned at the velocity nodal points of the vibrational energy waves which are transmitted along the wire/sleeve combination to cause detachment of an end section (not shown). The velocity nodal points, of course, are those locations in a mechanical wave where there is little or no movement or velocity of the wave-carrying structure, whereas the locations midway between the supports 98 are the antinodes where there is maximum movement of the wave-carrying structure. By providing the supports 98, the wire and sleeve are held apart to thereby prevent friction between the two as the vibrational energy wave travels down the

for example, of stainless steel, is hollow, allowing therapeutic fluid and drugs to pass therethrough. A plurality of cuts (not shown) may be made in the end section 201 to provide for coiling and configuring the end section as desired for ultimate disposition at a target site in a body passageway. A cut or diameter reduction 202 is also formed in the hollow wire 200 to provide the desired discontinuity. A bottom mass 203 is added below the cut with an adhesive 206 to further exaggerate the discontinuity. The bottom mass 203 is preferably made of platinum.

FIG. 11B shows a side view of another embodiment of a wire with a discontinuity similar to FIG. 11A. This embodiment has a top mass 208 added adjacent to the cut 202 with an adhesive 206 to further exaggerate the discontinuity. The top mass 208 is preferably made of platinum, and the adhesive 206 can be epoxy or cyanoacrylate. Alternatively, the mass may be affixed by a welded or soldered connection.

FIG. 11C is a side view of a hollow wire 200 made, for example, of stainless steel, to allow therapeutic fluid or drugs to pass through to a target body site. A plurality of top masses 210 are attached adjacent to the cut 202 with an adhesive 212 to further exaggerate the discontinuity. The plurality of masses 210 are preferably made of platinum. It will be apparent that the wire of FIG. 11C could be alternatively formed with a plurality of bottom masses attached below the cut 202 in the hollow wire 200, in the manner of FIG. 11A.

The hollow wire can also be formed without through-cuts to provide a hollow detachment site that does not allow fluids to escape from the lumen of the hollow wire. As shown in FIG. 12A, a hollow wire 200 with a central lumen 214 is formed with an annular cut 216, or alternatively a pair of oppositely disposed straight cuts, forming a discontinuity, that does not extend to the lumen. A coil 218 which wraps around the outside of wire 200 is disposed adjacent cut 216 and attached with adhesive 220, to exaggerate the effect of the discontinuity. Alternatively, as shown in FIG. 12B, a coil 222 may be disposed within lumen 214 of the wire, adjacent the cut 216.

FIG. 13 is a side cut away view of a catheter 304 and guide wire combination 302 with a wide cut 322 to allow therapeutic fluid to pass through a

Therapeutic fluid is delivered to a target body location through the catheter 304. The fluid passes through the catheter 304 and into the wide cuts 322. The therapeutic fluid is retained within the catheter 304 due to the slip fit of the catheter containment sleeve 314 just past the wide cuts 322. A fluid passage 324 is formed between the platinum masses 318 in the end section 312 to allow fluid to flow out the distal end 313. The platinum masses 318 are attached to the inside of the distal end 312 with an adhesive 320. Upon completion of the site specific fluid or drug delivery, an ultrasonic transducer is used to fatigue the wide cut 322. Upon the localized fracture of the wide cut 322, the delivery section of the device 300 can be removed. The catheter containment sleeve 314 slides off the wire end 313 via a hydrophilic interface 316, and this leaves the wire end 313 inside the body. The catheter 304 and the guide wire 302 are then removed.

Naturally, it will be desirable for a user of this invention to know immediately when the end section of a wire has been detached from the wire so that the wire can be withdrawn from the body passageway. For each of the embodiments described above involving a delivery wire portion and an end section for ultimate detachment at a target site, the combinations of wire and end sections all have natural or resonant frequencies. Thus, when vibrational energy is applied to a wire, such as wire 16 in FIG. 1, the resonant frequency of the combination of the wire 16 and end section 16a will have a certain resonant frequency which can be detected by conventional spectrum analysis methods.

Figure 15A depicts a system for monitoring and displaying this resonant frequency, and for determining when detachment has occurred. This system shown in FIG. 15A is consistent with, but more detailed than that shown in FIG. 1. The system generally comprises an ultrasonic transducer 400 connected to a detachable coil device 16 having a detachable end section 16a, a spectrum analyzer 28, a frequency generator 24, and a power amplifier 402. The ultrasonic transducer 400 is driven with a periodic waveform produced by the frequency generator 24 and amplified by the power amplifier 402. The electrical impedance, z (a complex ratio of voltage to current flow) of the transducer is a function of frequency, and of the physical device driven by the transducer (the detachable coil device 16). The impedance of the transducer is measured by the spectrum

art without departing from the spirit and scope of the present invention and the appended claims are intended to cover such modifications and arrangements.

8. Apparatus as in claim 7, wherein the at least one discontinuity further comprises an abrupt mass of material on the hollow wire.

9. Apparatus as in claim 8, wherein the abrupt mass comprises a coil disposed on the outside of the wire.

10. Apparatus as in claim 8, wherein the abrupt mass comprises a coil disposed inside the hollow passage of the wire.

11. Apparatus as in claim 1, wherein the delivery means for delivering the therapeutic flow is a catheter surrounding the elongate wire, said catheter extending past the at least one discontinuity to the distal end section for delivering therapeutic fluid to the target body location.

12. Apparatus as in claim 11, wherein the distal end of the elongate wire is hollow to allow the flow of therapeutic fluid from the catheter through a cut in the wire and out the hollow distal end section into the target body location.

13. Apparatus as in claim 11, wherein the at least one discontinuity comprises an abrupt mass of material in the hollow distal end section of wire.

14. Apparatus as in claim 13, where the abrupt mass inside the hollow distal end section is further comprised of a platinum mass attached with an adhesive.

15. Apparatus as in claim 13, where the abrupt mass inside the hollow distal end section comprises a coil.

16. Apparatus as in claim 1, wherein the distal section of the wire is a nickel titanium tube that allows therapeutic fluid to flow through the tube.

17. Apparatus as in claim 1, wherein the wire comprises:

3) an adhesive joint binding the wire and the end section, such that the metal winding strengthens the adhesive joint; and

4) at least one cut in the hollow tube to allow the passage of a therapeutic fluid through the distal end section;

b) a catheter surrounding the elongate wire and extending past the discontinuity in the distal end section for delivering therapeutic fluid to the target body location; and

c) means for selectively applying vibrational energy to the wire to travel to the discontinuity and cause detachment of the distal end section.

22. Apparatus as in claim 21, further comprising a platinum mass disposed within the hollow distal end section, and disposed to allow therapeutic fluid to flow through the distal end section and the at least one cut, wherein the cut aids in detaching the distal end.

23. Apparatus as in claim 21, wherein said at least one cut is deep enough to allow therapeutic fluid to flow through the cut.

24. Apparatus as in claim 21, wherein said at least one cut is wide enough to allow therapeutic fluid to flow through the cut.

25. Apparatus as in claim 21, wherein the wire is constructed of stainless steel, and wherein said distal end section is constructed of nickel titanium alloy.

26. Apparatus as in claim 21, wherein said at least one cut is cut to a depth to readily cause rupturing of the distal end section at the location of the at least one cut when the vibrational energy is applied thereto.

27. Apparatus as in claim 21, wherein the vibrational energy applying means comprises an ultrasound generator coupleable to the proximal end of the wire.

h) monitoring the change in impedance to determine when the detachable end section of the wire has detached; and

i) generating a humanly discernable signal for indicating to a user when detachment has occurred.

32. A system for determining when detachment of a detachable distal end section of a wire device has occurred, comprising:

a) means for converting electrical signals into mechanical vibration of the wire device;

b) means for producing a periodic waveform of a selected frequency;

c) means for amplifying the periodic waveform and delivering the waveform to the means for converting electrical signals into mechanical vibration;

d) means for measuring the impedance of the means for converting electrical signals into mechanical vibration; and

e) means for monitoring the change in impedance of the means for converting electrical signals into mechanical vibration to determine when the detachable distal end section of the wire device has detached, and generating a humanly discernable signal for indicating to a user when detachment has occurred.

33. The system as in claim 32, further comprising:

a) a transducer connected to a proximal end of the wire device for converting the electrical signals into mechanical vibration of the wire device;

b) a frequency generator for producing the periodic waveform;

c) a power amplifier for amplifying the periodic waveform produced by the frequency generator and delivering the waveform to the transducer;

d) a spectrum analyzer for measuring the impedance of the transducer and for generating a plot of impedance versus frequency of the waveform exhibiting resonant peaks due to the physical characteristics of the wire device; and

e) means for displaying the plot of impedance versus frequency of the waveform in a humanly discernable form, whereby a user may detect when the detachable distal end section of the wire device has detached by discerning changes in the resonant peaks of the plot.

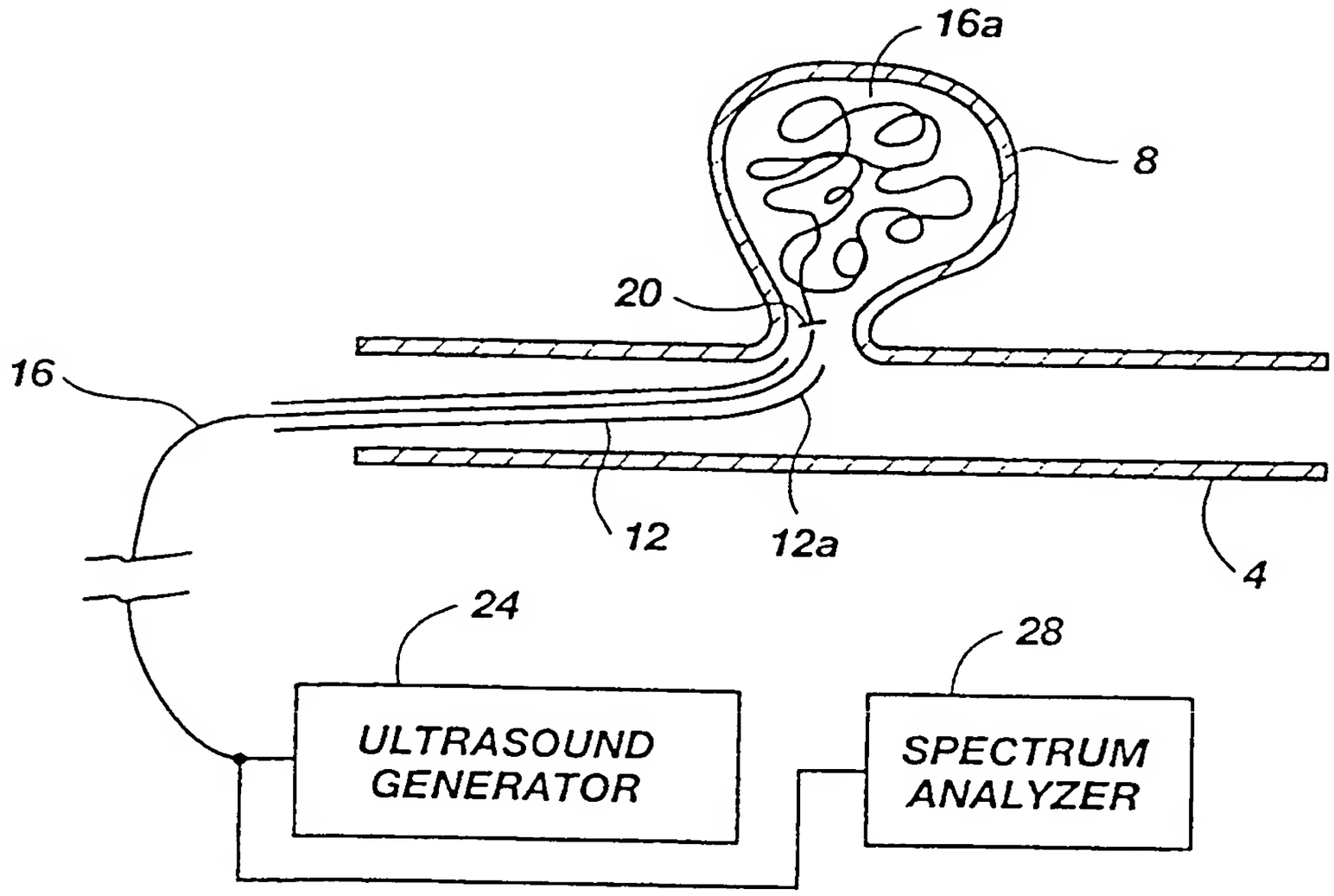


Fig. 1

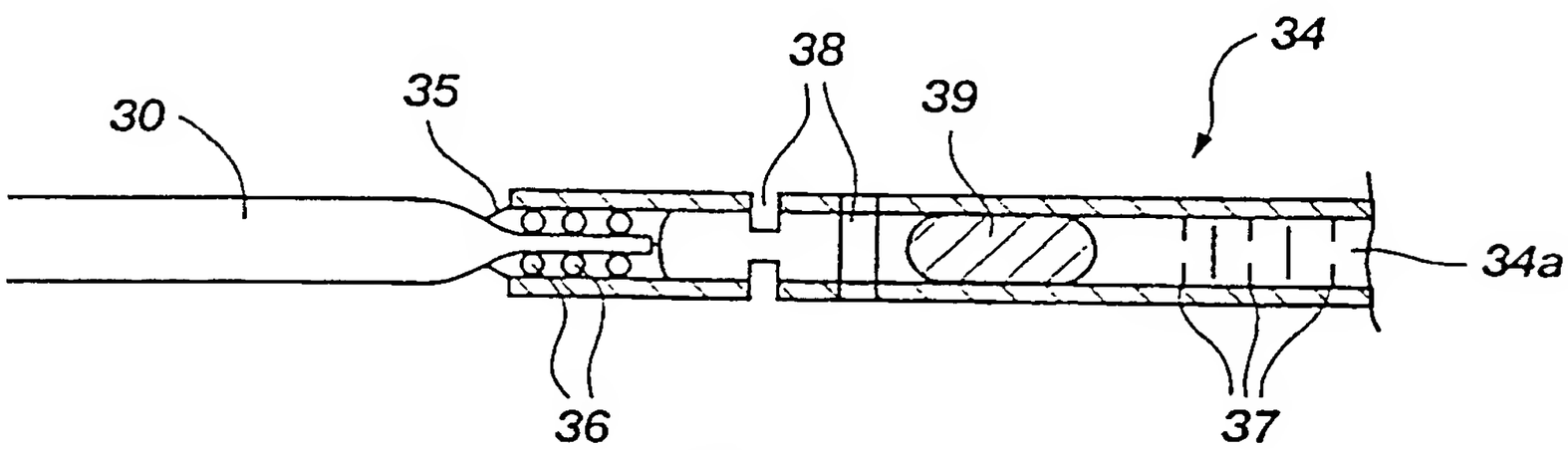


Fig. 2

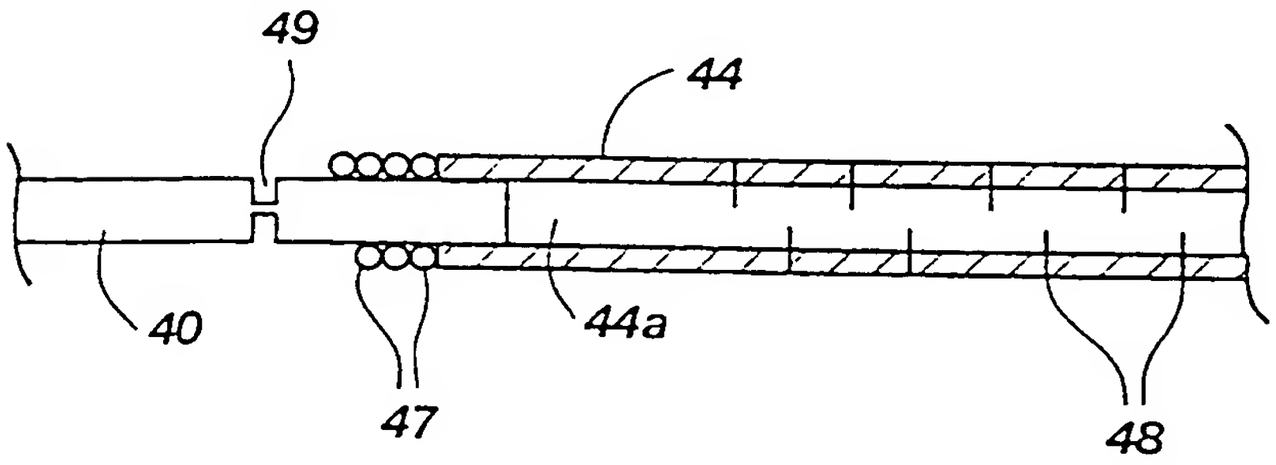


Fig. 3

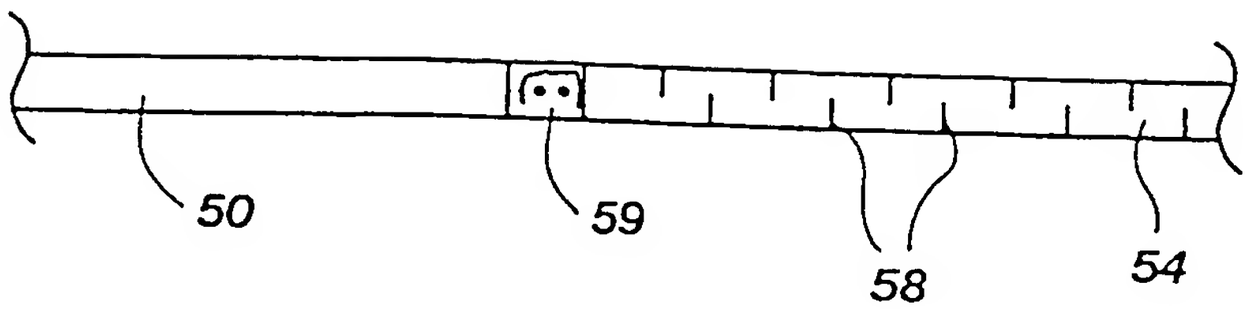


Fig. 4A

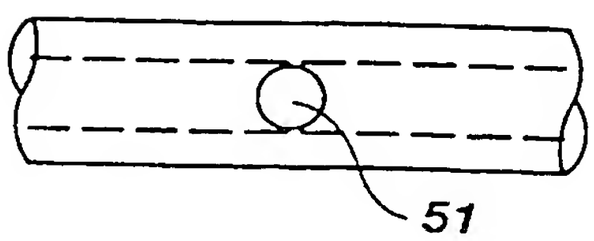


Fig. 4B

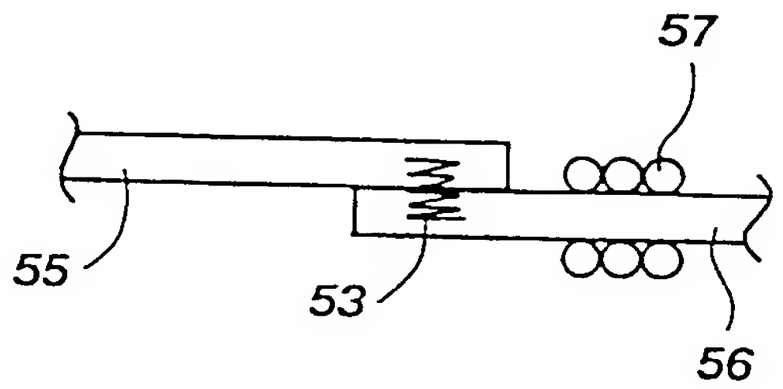


Fig. 4C

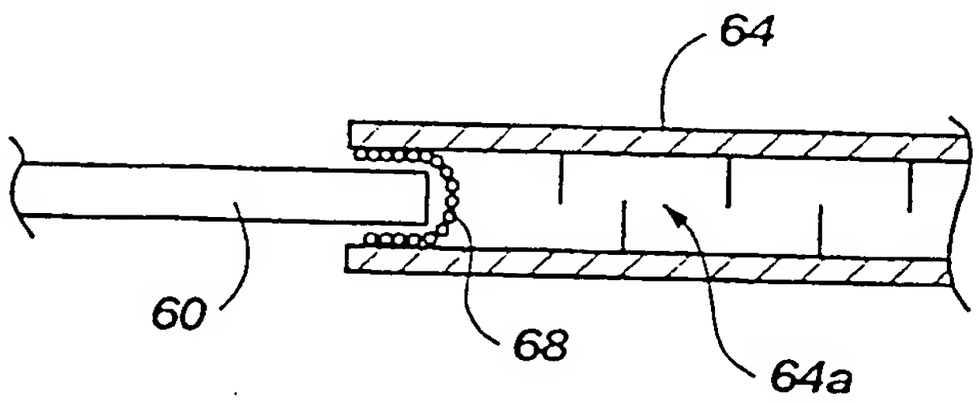


Fig. 5

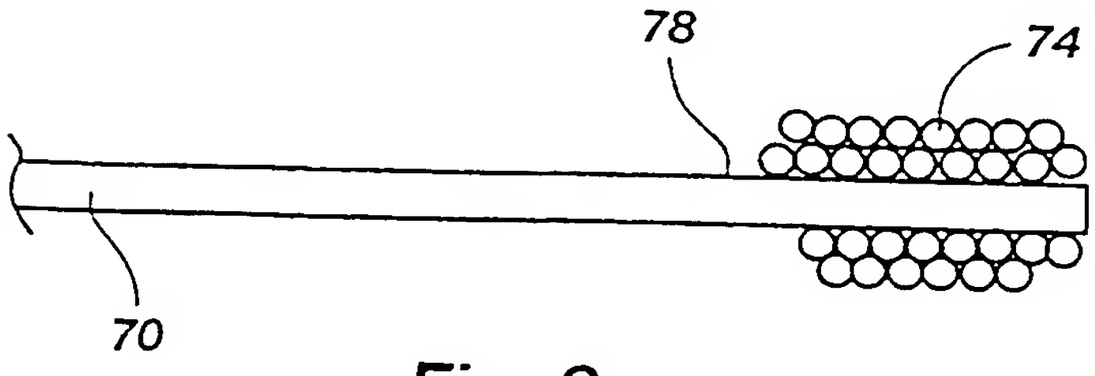


Fig. 6

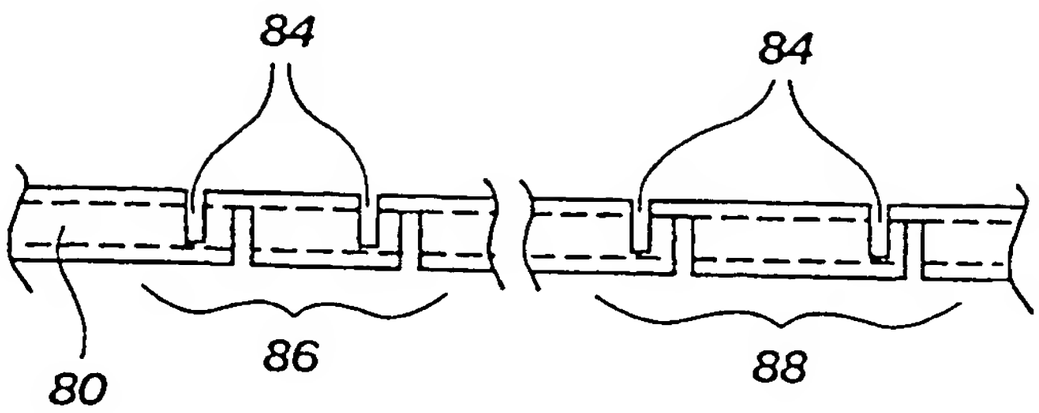


Fig. 7

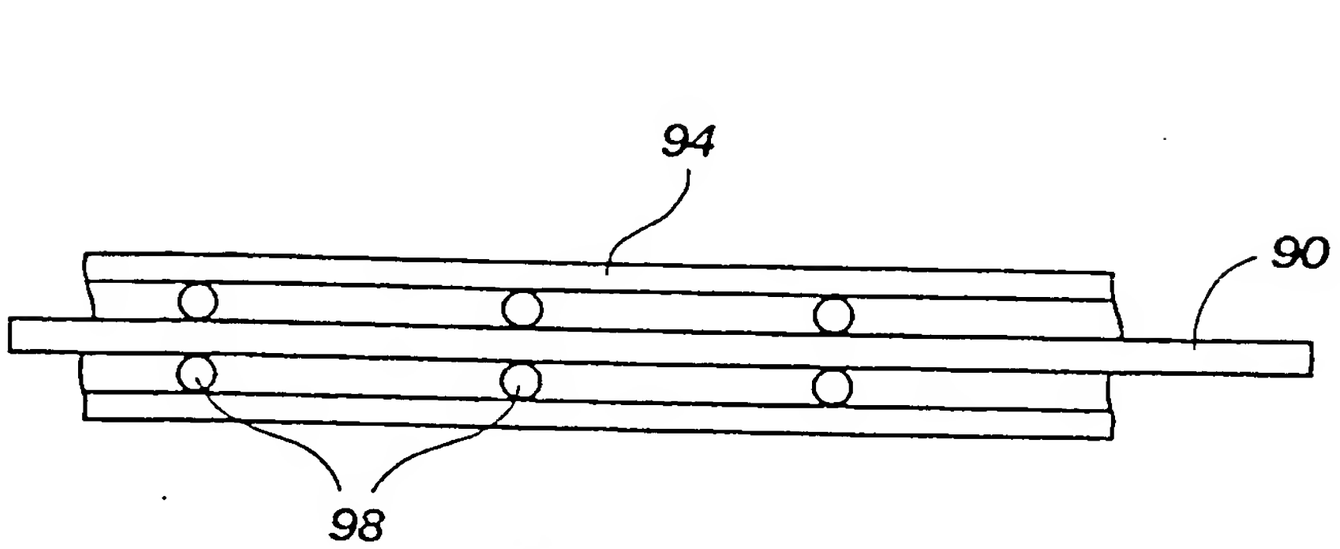


Fig. 8

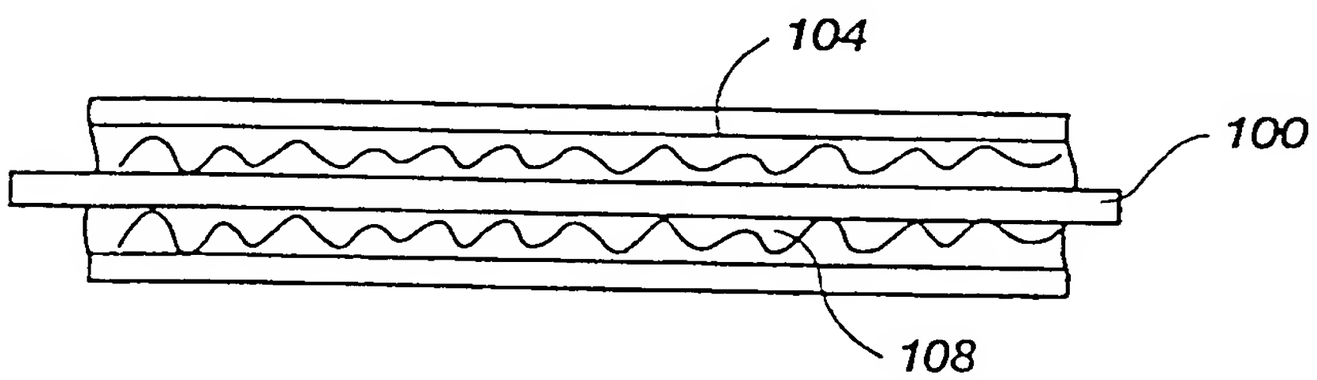


Fig. 9

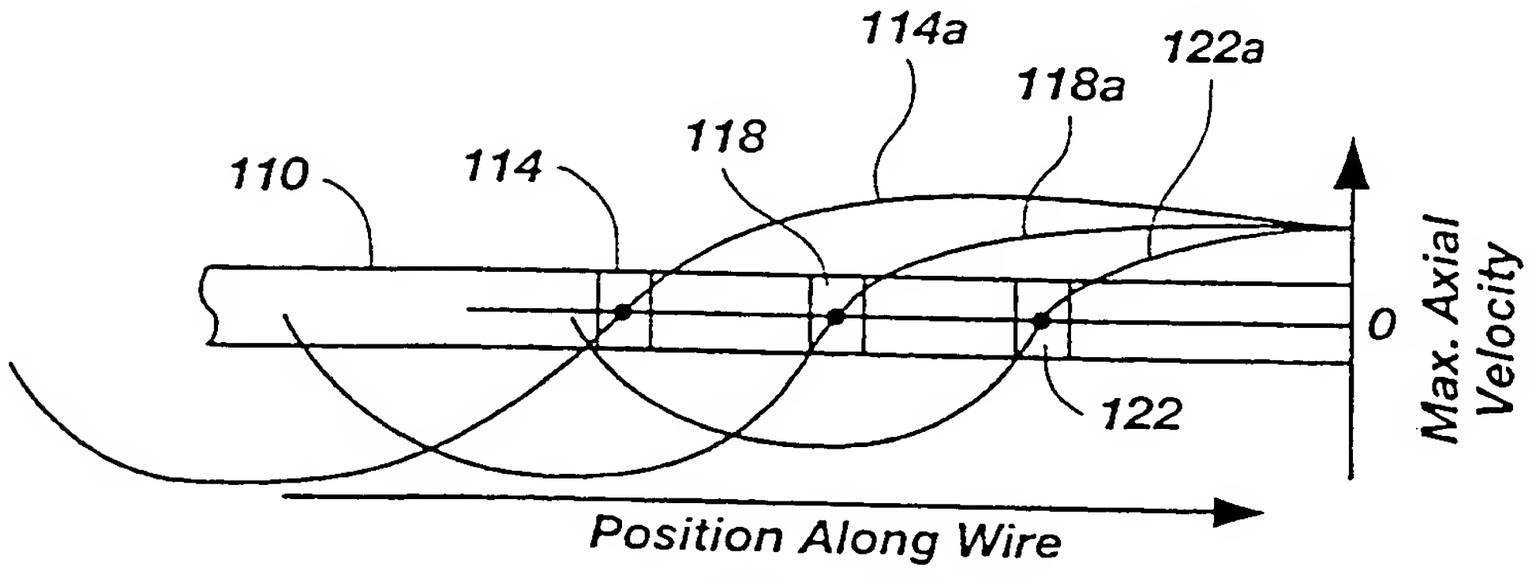


Fig. 10

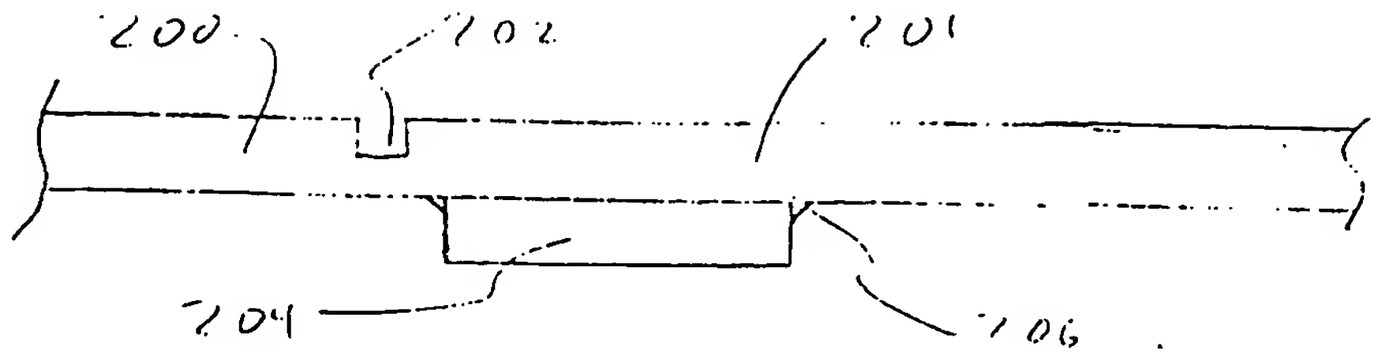


FIG 11A

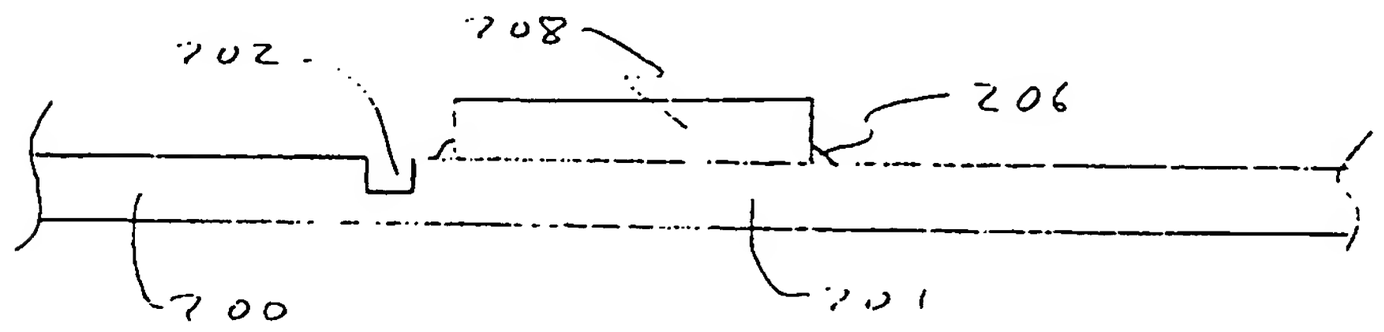


FIG. 11B

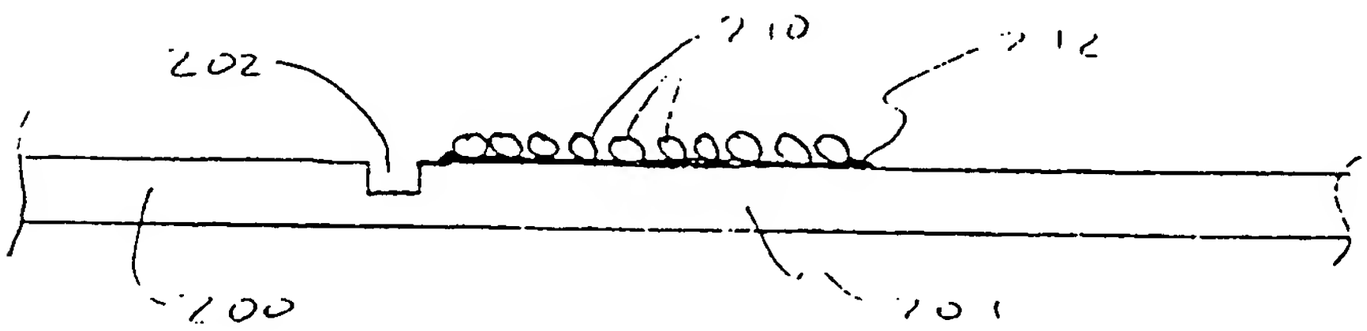


FIG. 11C

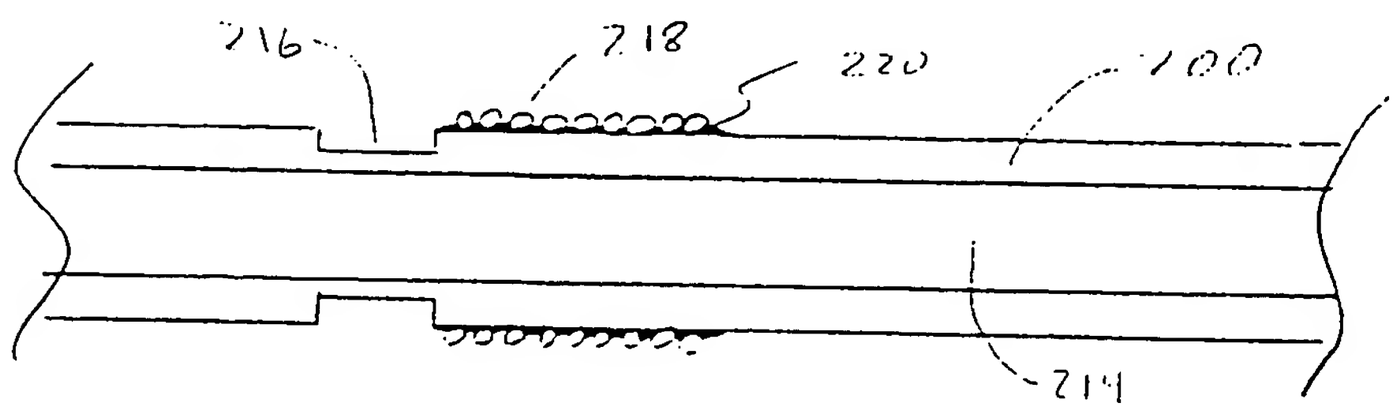


FIG. 12A

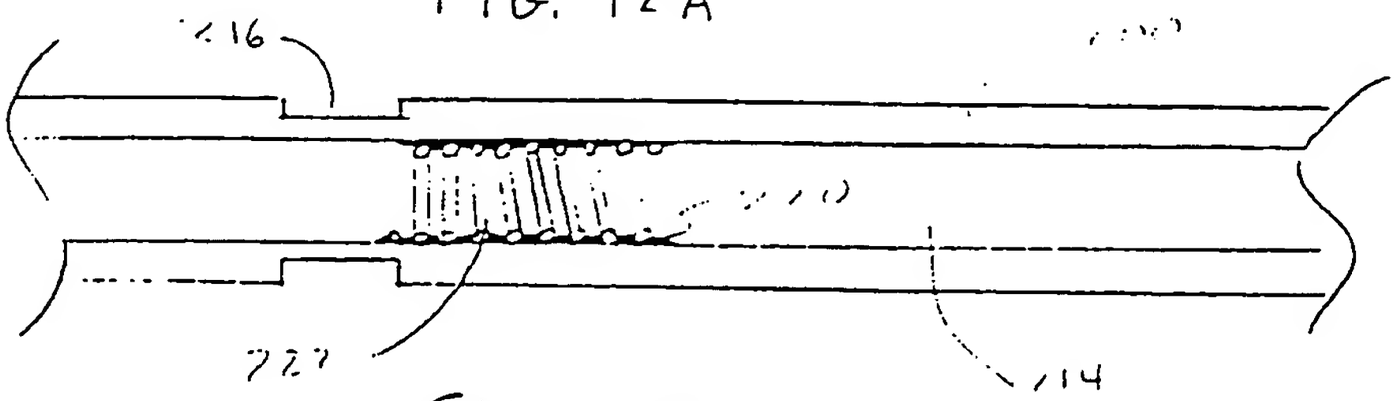
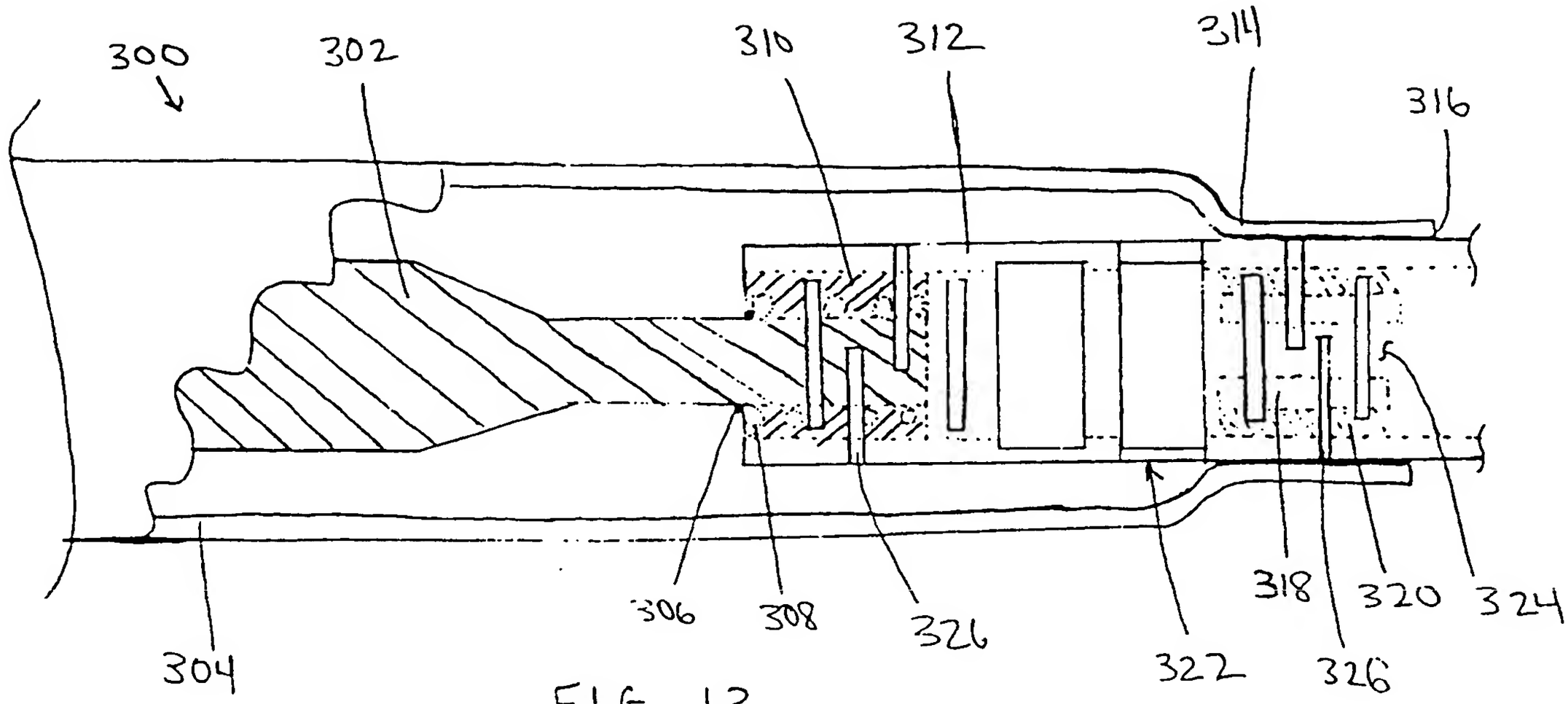


FIG. 12B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302
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326

FIG. 13

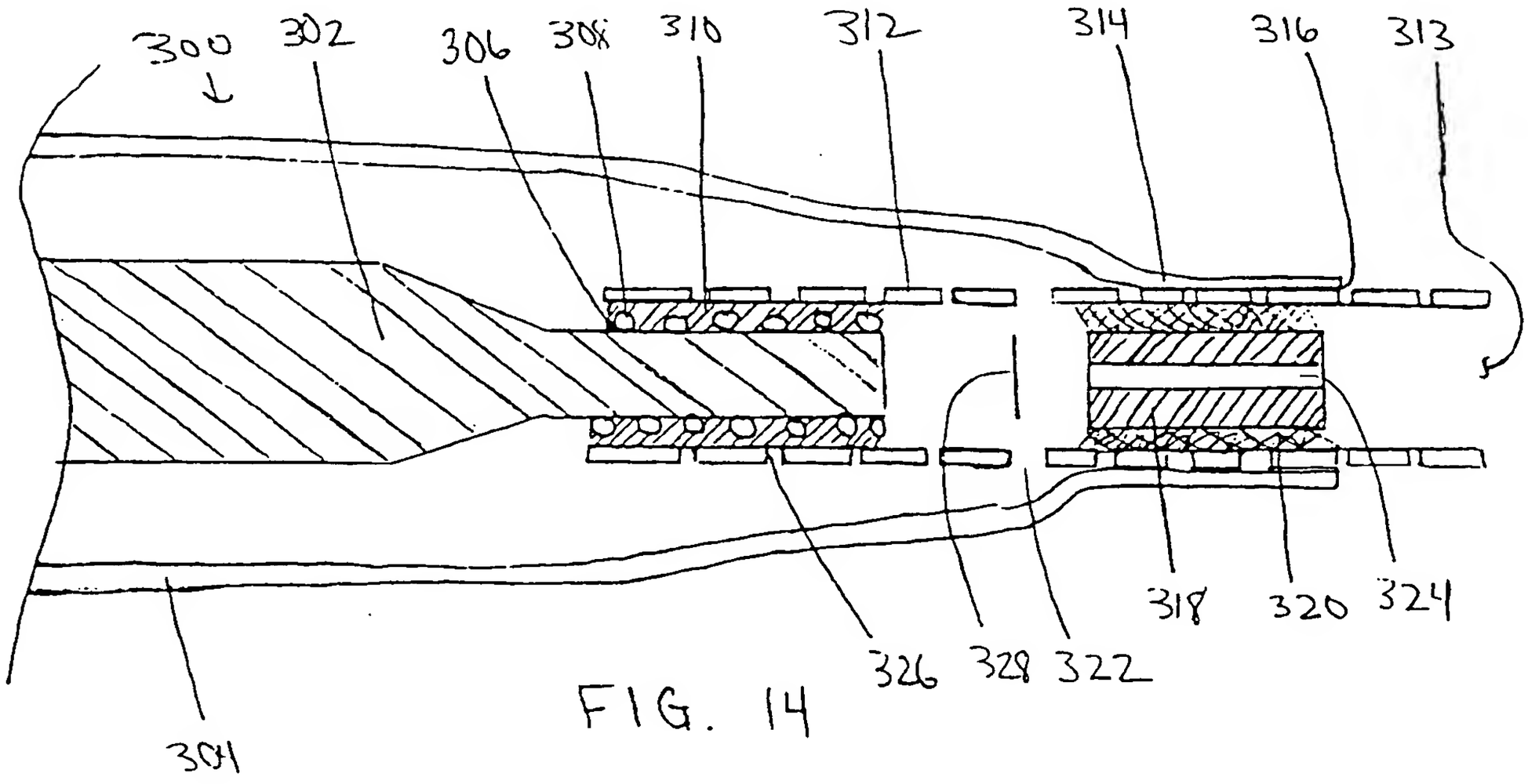
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FIG. 14

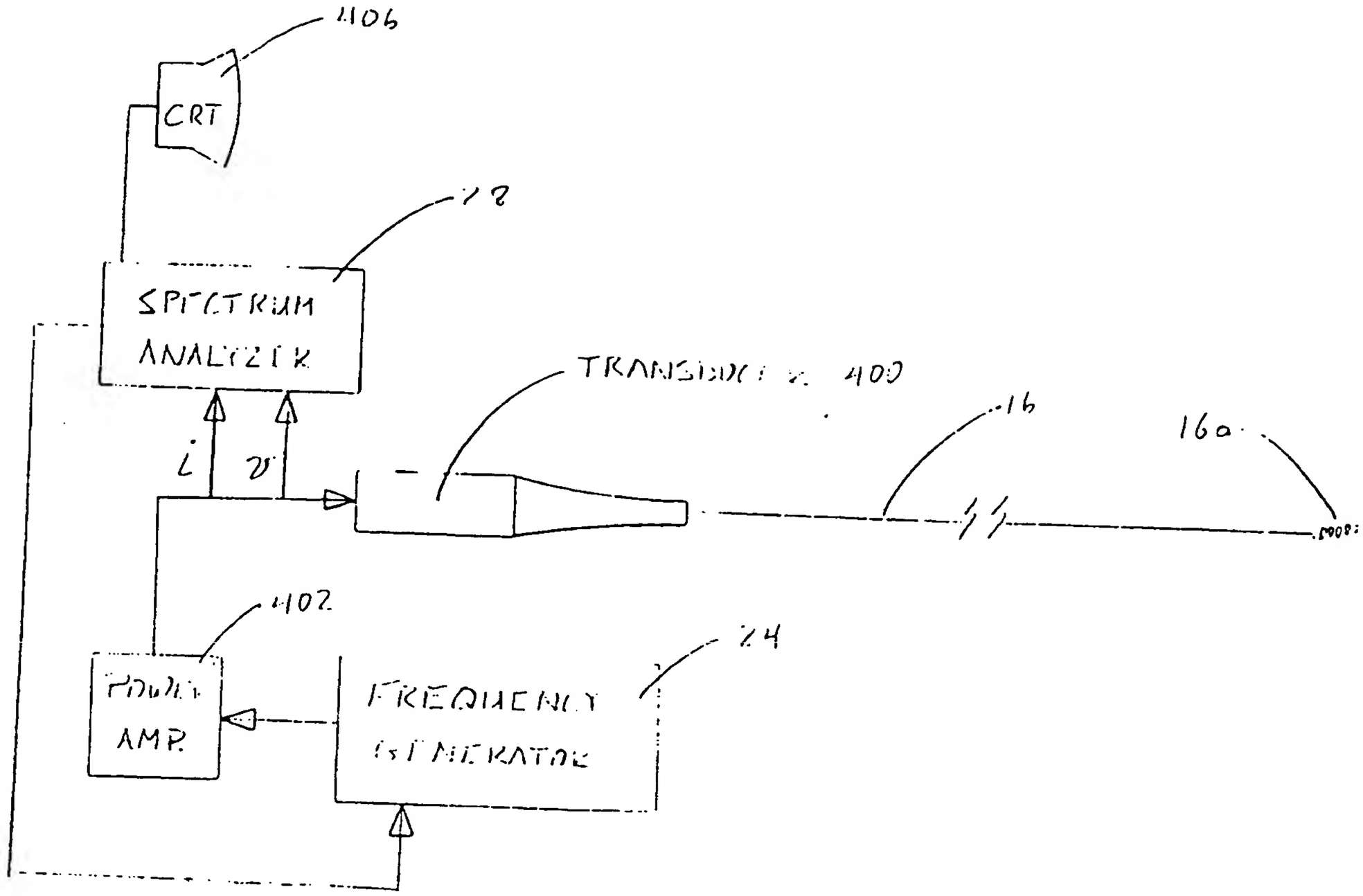

FIG. 15A

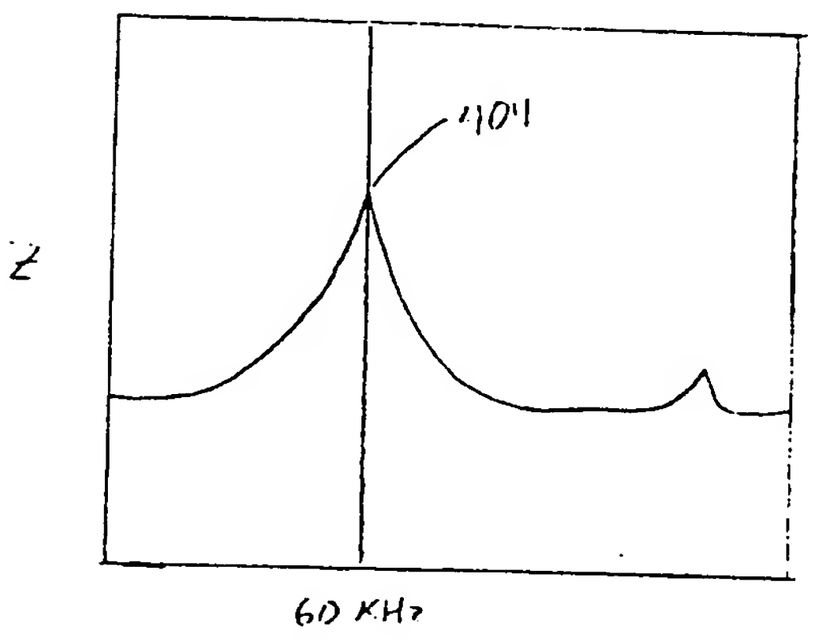

FIG. 15B

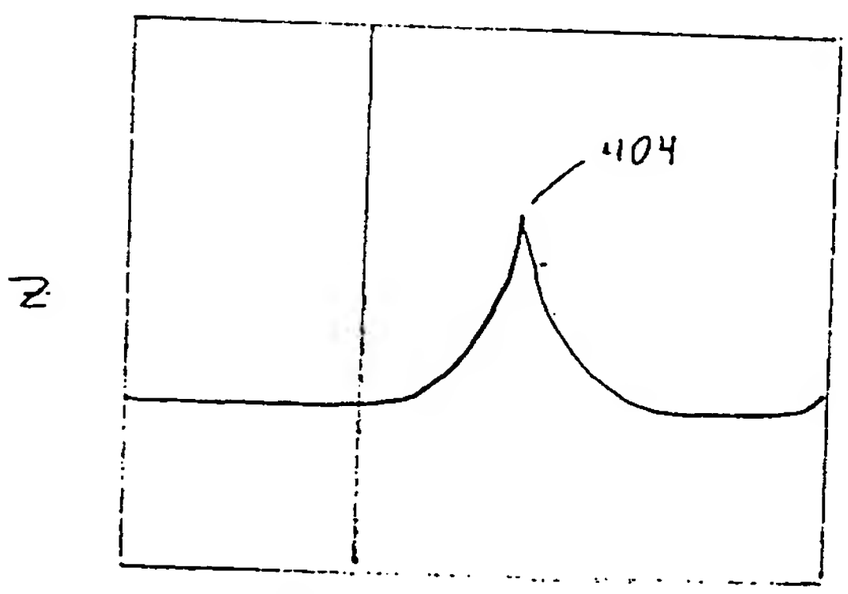

FIG. 15C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/41219

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61M 31/00
US CL :604/57
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/57, 22, 19, 500, 93.01, 95.04,164.13, 264,523,528; 623/1.1; 606/191,1,108,151,194,195

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST:(vas$ adj occlu$) and detach$; ultraso$ and (vaso adj occlu$); class/sub and ultraso$ and (wire or guide adj wire)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,749,894 A (ENGELSON) 12 May 1998, see specification, figures 7-9, 10A-10D.	1-3, 7, 11, 12, 16, 21
A	US 5,964,797 A (HO) 12 October 1999, see specification	1-3, 7, 11, 12, 16, 21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 FEBRUARY 2001	Date of mailing of the international search report 26 MAR 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CRIS L. RODRIGUEZ Telephone No. (703) 308-2194

Form PCT/ISA/210 (second sheet) (July 1998)*